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(1)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/044,696	03/18/98	BARCHFELD	G 1393,002

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HM12/0607

EXAMINER

DEVI, S

ART UNIT

PAPER NUMBER

1641

8

DATE MAILED:

06/07/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary	Application No. 09/044,696	Applicant(s) Barchfeld et al.
	Examiner S. Devi, Ph.D.	Group Art Unit 1641

Responsive to communication(s) filed on Jul 30, 1998

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-30 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

Claims 1-30 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Election / Restriction

1) **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Donald E. Adams, Ph.D., Supervisory Patent Examiner at Donald.Adams@uspto.gov or 703-308-0570. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

2) Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-14, drawn to a parenteral adjuvant composition comprising a detoxified mutant of a bacterial ADP-ribosylating toxin and an antigen, classified in class 424, subclass 78.1
- II. Claims 15-18, drawn to a method of making a parenteral adjuvant composition comprising combining a detoxified mutant of a bacterial ADP-ribosylating toxin with an antigen, classified in class 435, subclass 69.1
- III. Claims 19-30, drawn to a method for immunizing a subject by parenterally administering an adjuvant comprising a detoxified mutant of a bacterial ADP-ribosylating toxin and an antigen, classified in class 424, subclass 236.1

3) Inventions I, II and III are distinct from one another. Inventions I and II are related as product and process of making the product. The inventions are distinct if either **or** both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case, the method of invention II can be used to make other and materially different product such as a non-adjuvant mutant toxin, or a non-parenteral or mucosal adjuvant.

Inventions I and III are related as product and process of using the product. The

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inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). In the instant case, the product of invention I can be used, for example, as a coating antigen in a materially different process such as a diagnostic assay. The process of invention II can be practiced with another materially different product, for example, a bacterial ADP-ribosylating toxin-specific antiserum via passive immunization.

Inventions II and III are directed two distinct methods which differ in method parameters, method steps, reagents used and ultimate goals accomplished.

Because these inventions are distinct for the reasons given and have acquired a separate status in the art as shown by their different classifications/subclassifications and divergent subject matters, restriction for examination purposes as indicated is proper.

4) The instant application contains claims directed to patentably distinct species of the claimed invention. Election to one of the following species of mutant toxin, which are structurally, functionally and immunologically different, is required:

(A) (a) Cholera toxin (CT); (b) Pertussis toxin (PT) and (c) *E. coli* heat-labile toxin (LT), recited in claims 2-4, 8-10, 20-22, and

(B) (a) LT-K63 and LT-R72; (b) CT-S109 and (c) PT-K9/G129 recited in claims 4, 10 and 22.

5) Applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

6) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7) Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission

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may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8) Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filled petition under CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

9) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi whose telephone number is (703) 308-9347. The Examiner can normally be reached on Monday to Friday from 7.45 a.m. to 4.15 p.m. A telephone message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May 1999


JAMES C. HOUSEL 6/7/99
SUPERVISORY PATENT EXAMINER